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Pronamide: Position Document 4

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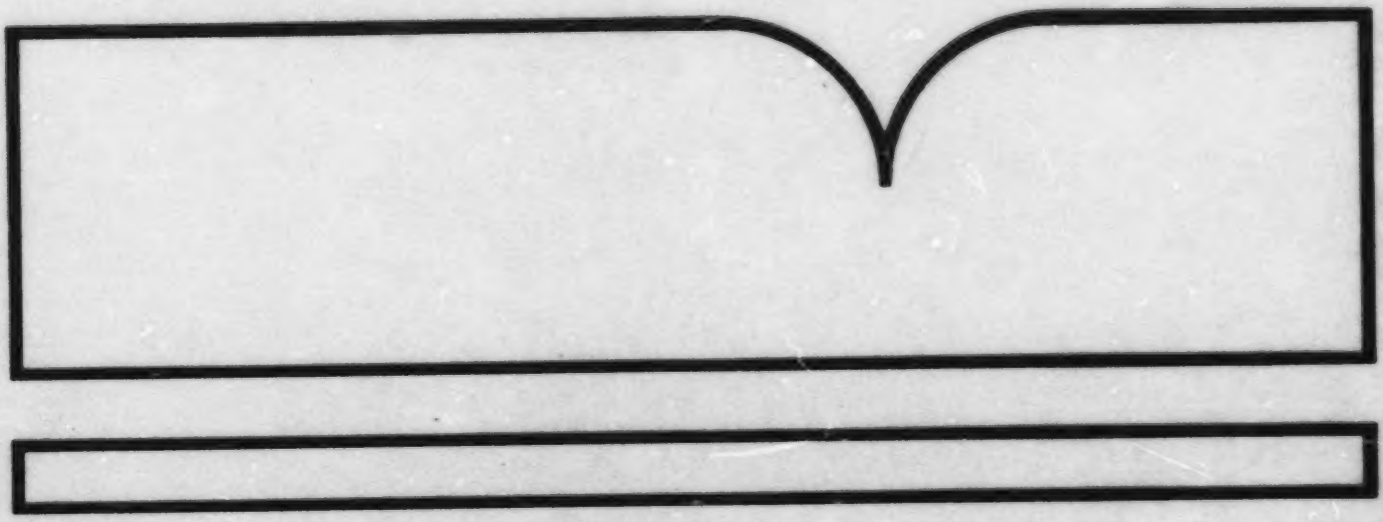

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I. Introduction

Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended (7 U.S.C. 136 et seq.), the Environmental Protection Agency (EPA or "the Agency") regulates all pesticide products. FIFRA, Section 6(b), authorizes the Administrator of EPA to issue a notice of intent (1) to cancel the registration or (2) to change the classification of a pesticide product if in his judgement either the pesticide or its labeling "does not comply with the provisions of [FIFRA] or, when used in accordance with widespread and commonly recognized practice, generally causes unreasonable adverse effects on the environment...." FIFRA, Section 3(c)(6), authorizes the Administrator to deny any application for pesticide registration which does not meet the statutory standards for registration.

To implement its authorized functions, the Agency has designed the Rebuttable Presumption Against Registration (RPAR) process (described in 40 CFR 162.11), which involves gathering data on the risks and benefits associated with the use of suspect pesticides. By allowing all interested parties to participate by submitting information, the process enables EPA to make balanced decisions concerning problem pesticides.

On May 20, 1977, the Agency issued an RPAR Notice (42 FR 25906) for all pesticide products containing pronamide on the basis that pronamide had been shown to be oncogenic in male mice. A detailed Position Document 1 accompanied this notice.

On January 15, 1979, the Agency issued Position Document 2/3 for pronamide and published a Notice of Determination and announced the availability of the Position Document in the Federal Register (43 FR 3083). In Position Document 2/3, the Agency analyzed the rebuttals it received in response to the original RPAR notice, presented its analysis of both risks and benefits associated with the uses of pronamide, and proposed a decision to conclude the RPAR process.

In Position Document 2/3, the Agency recommended Option 4 and concluded that the benefits of pronamide's use outweighed the risks if the following modifications to the terms and conditions of registration were adopted:

1. Pronamide would be classified as a restricted use pesticide, and applicator certification would be required.
2. The use of protective clothing during the mixing and the application of pronamide would be required.
3. Pronamide (wettable powder) must be formulated in water-soluble bags.
4. Hand spray use would be cancelled.

5. The tolerance on lettuce must be revised from 2 ppm to 1 ppm to lower the dietary exposure, with label restrictions limiting the use to pre-emergent use only with a 60-day time-to-harvest interval (THI).

6. A monitoring report on residues in milk from pronamide use on alfalfa would be required at 5-year intervals coincident with reregistration.

40 CFR 162.11 requires that the Agency submit notices issued pursuant to FIFRA, Section 6, to the Secretary of the U.S. Department of Agriculture (USDA) for comment on the impact of the proposed action on the agricultural economy [Section 6(b)] and to the FIFRA Scientific Advisory Panel (SAP) for comment on the impact of the proposed action on health and the environment [Section 25(d)]. The Agency is required to submit these documents to the Agriculture Secretary and the SAP at least 60 days before sending them to registrants or making them public. The Secretary and the SAP are invited to comment in writing within 30 days of receiving the notice. The Agency is required to publish their written comments if submitted within 30 days of the receipt of the Notice and the EPA Administrator's response to these comments.

Although not required to do so under the statute, the Agency has decided that it is consistent with the purposes of the RPAR process and the Agency's overall policy of open

decision-making to also afford registrants and other interested persons an opportunity to comment on the bases for the proposed action while it is under review by the Secretary of Agriculture and the SAP. The Position Document was therefore made available to all interested parties for comment.

The Agency received comments from six parties in response to the notice of January 15, 1979. Their comments are addressed and analyzed in Section II of this document. Section III summarizes the Agency's decision concerning pesticide products containing pronamide. SAP's response is reproduced in its entirety as Appendix A of this Position Document. USDA's response is reproduced in its entirety as Appendix B. All comments are available for review in the public file.

II. Analysis of Comments

In response to the publication of the Notice of Determination and Position Document 2/3, EPA received comments from six parties: pesticide manufacturers Rohm and Haas Co. (2[30000/14B]) and PPG Industries (5[30000/14B]); an individual who signed her letter "Karen" (1[30000/14B]); Gordon Harvey, University of Wisconsin (3[30000/14B]); the Secretary of Agriculture (5[30000/14B]); and the SAP, which reviewed the entire decision.

A. Comments Relating to Risk

1. Background

The Agency conducts a qualitative and a quantitative risk assessment based on its evaluation of the hazard of the pesticide in conjunction with a best estimate of the potential for human and environmental exposure to the chemical. The magnitude of the carcinogenic hazard of any pesticide (i.e., the number and types of tumors it causes) is determined from chronic feeding studies. The most sensitive valid feeding study available serves as the basis for estimating the degree of hazard. For pronamide, an 18-month mouse oncogenicity study which demonstrated a positive response in male mice, was used as the basis for risk extrapolation. This study provided the only evidence that pronamide is likely to be a human carcinogen.

The potential for human and environmental exposure to pronamide was derived from available data and assumptions about work place practices, current agricultural practices, dietary habits, and body weight. The exposure figures obtained represented the Agency's best estimate of the exposure potential of pronamide. Although there are uncertainties in these estimates, this approach allows a measurement of risk to the population at large and subgroups with specific exposure potentials, as well as a measurement of risk comparative to that posed by other carcinogens.

2. Extrapolating Risk to Human Populations

Rohm and Haas Co. (2[30000/14B]) claimed that EPA's assessment of risk is unfairly based on a progression of worst-case and most conservative assumptions. The Agency rejects this contention. In its Interim Procedures and Guidelines for Health Risk and Economic Impact Assessments of Suspected Carcinogens [Cancer Guidelines] (41 FR 21402, et seq., May 25, 1976), the Agency adopted a framework for decision-making which is fundamentally conservative in approach due to the irreversibility of the effect and which demands that caution be exercised wherever risk to public health is concerned.

3. Calculating Dietary Exposure

Rohm and Haas objected to the Agency's use of the tolerance levels (i.e., maximum permissible residues) in calculating dietary exposure, instead of the amounts of actual residues measured in controlled experiments or monitoring studies.

EPA finds the Rohm and Haas' objection unmeritorious. In estimating risk from dietary exposure, the Agency must use the best available measurements or estimates of exposure. Wherever valid and sufficient residue data are available they of course represent the best index of exposure. In the absence of such residue data, however, the tolerances established for various foodstuffs represent the best and

most conservative estimates of the levels of pesticide residues to which the populace may be exposed. Likewise, use of the limit of analytical sensitivity (detection limits) represents a conservative and reasonable approach to dietary residue estimates where the available data indicate no likelihood that actual residues exceed the detection level. The Agency has followed the approach of using the best available measurements to determine dietary exposure levels and has used tolerance levels only when data were not available to allow a determination of actual residues.

In determining exposure to pronamide from dietary sources, the Agency reviewed residue data for established tolerances on lettuce, on meat, milk, and eggs, and on berries. In the case of lettuce, available data on residues from field monitoring studies (0.1 ppm) and from a study of radioactively labeled pronamide (0.8 ppm) demonstrated that actual residues were likely to be below the tolerance level (2.0 ppm). The Agency believes that the value of 0.8 ppm obtained in the study of radioactively labeled pronamide best represents a conservative estimate of dietary exposure from lettuce. In the case of meat, milk, and eggs, the Agency used the limit of analytical sensitivity (0.01 ppm) as a measure of exposure because the data indicate little likelihood that residues will exceed the value. In the case of berries, the Agency used the tolerance level

(0.05 ppm) for exposure estimates because there were insufficient data on which to predict a level of residues below the tolerance level, and available data indicated that residues may exceed the limit of analytical sensitivity.

Rohm and Haas also objected to EPA's use of the residue value of 0.8 ppm obtained from controlled field studies in calculating the dietary risk from lettuce. The registrant claimed that only part of this residue was the parent compound (pronamide) because degradation and metabolism had reduced the actual amount of parent compound. The Agency rejects this argument and holds that the calculation based on the value of 0.8 ppm does indicate a reasonable upper bound of expected residues. Rohm and Haas was probably correct in claiming that not all of the 0.8 ppm is parent compound. However, the company did not report, nor is the Agency aware of, data that demonstrate that pronamide is the only oncogenic agent among its degradation products and metabolites. Therefore, using the total residue value 0.8 ppm represents a conservative but reasonable approach to calculating oncogenic risk.

4. Estimating Applicator Exposure

Rohm and Haas objected to the Agency's use of extrapolated data, rather than data from actual measurements, to estimate the risk to applicators.

EPA rejects Rohm and Haas' argument because the extrapolated data represent the most reliable data available to the Agency. In developing its exposure assessment, the Agency analyzed three sets of data to determine the quantity of pronamide dust and spray to which applicators may be exposed. Two of these analyses relied on extrapolations of the data presented in studies which used other pesticides with formulations similar to that of pronamide (Jegier, 1964; and Wolfe, 1974). The third analysis used data from a pronamide study. The results of all three analyses were included in PD 2/3. However, limitations in the study performed with pronamide[1/] precluded the use of data from this study as a reliable estimate of exposure, and the Agency was therefore forced to rely on extrapolated data. The middle range of exposure values extrapolated from Jegier's data was used rather than the extremely conservative values obtained from extrapolation of Wolfe's data.

To again attempt to show that the Agency overstated applicator exposure, Rohm and Haas submitted, on April 24, 1979 (Krzeminski, 1979), an additional study designed to determine the exposure of applicators with and without protective clothing. The study consisted of two tests in which applicators wore protective clothing of the type specified in PD 2/3 and two tests in which applicators wore no protective clothing. (The same two applicators were

1/ This study was performed with only one applicator and was not replicated.

involved in each test.) The Agency can not accept this study since it had a very limited data base (Day, 1979). The study also demonstrated a high degree of variability which further lessens its reliability for determining an average exposure to pronamide. Therefore, EPA again rejects Rohm and Haas' contention that the Agency has overstated applicator exposure.

Rohm and Haas also objected to the Agency's assumption that two people are involved in mixing and applying pronamide on alfalfa farms. The Agency rejects this contention. The assumption is based upon published data indicating that in fact there are, on an average, two workers on alfalfa farms. In keeping with the other conservative assumptions, it is reasonable to assume that both workers would be involved in the mixing and spraying of pronamide. Moreover, Rohm and Haas did not offer any data to support their contention that only one worker is used in mixing and spraying.

5. Risks of Alternate Pesticides

PPG Industries claimed that propham is not teratogenic, as reported in PD 2/3. EPA has again reviewed the data on which the original conclusion concerning teratogenicity in PD 2/3 was based, including an EPA study conducted by Dr. K. Diane Courtney at the Health Effects Research Laboratory, Research Triangle Park, North Carolina.

On the basis of this review, the Agency agrees that at this time, data on which to judge the teratogenicity of propham are insufficient.

PPG Industries also claimed that chloropropham is not as strongly oncogenic as indicated in PD 2/3. The Agency rejects this argument. As stated in the Cancer Guidelines, a positive initiation-promotion skin test constitutes evidence of oncogenicity--unless a valid animal feeding bioassay is submitted which is negative. The only available study on chloropropham is an initiation-promotion skin test performed on mice, the results of which are positive. EPA is unaware of any animal feeding bioassays for chloropropham. Moreover, in PD 2/3 the Agency merely reported the positive result of the available initiation-promotion skin test. No judgment was made concerning the potency of the potential oncogenicity of chloropropham.

B. Comments Relating to Benefits

1. Background

In assessing the benefits of the continued use of pronamide, the Agency evaluated the economic, social, and environmental effects which would result should any or all uses of the pesticide be cancelled. The benefits of continued use were weighed against the attendant risks.

The benefits analysis included a quantitative assessment of the impact of all possible EPA regulatory actions on crop production, prices of agricultural commodities, retail food prices - and the agricultural economy in general. The data which provided the basis for the benefits analysis were derived from information supplied by Rohm and Haas, the U.S. Department of Agriculture, and other interested parties.

2. Incomplete Assessment of Benefits

Rohm and Haas submitted in rebuttal to PD 1 a set of economic values which differed from those the Agency ultimately used for pronamide in PD 2/3. The most noticeable difference between the two assessments was in the area of minor uses (e.g., nursery stock and Christmas tree plantings), and the commenter's main concern was that EPA failed to address adequately these minor uses.

The economic analysis presented in PD 2/3 was based in part on data supplied by the USDA under a joint program to permit active USDA participation in benefits analyses. The analysis of minor use benefits was, however, qualitative rather than quantitative, simply because quantitative data were insufficient. Rohm and Haas did submit some quantitative data; however, because EPA in its analysis was unable to substantiate the data, the Agency chose to address the minor uses qualitatively.

Aside from the problem of substantiation, moreover, the quantitative data supplied would in all likelihood not have changed the regulatory decision.

3. Benefits of Alternative Pesticides

PPG Industries objected to the Agency's "intimations that detract from the usefulness of [the] alternatives" propham (IPC^{R}) and chloropropham (Chloro IPC^{R}).

PPG contended (1) that application methods for pronamide are not unique, since wet weather affects the use of all pesticides; (2) that mechanical and hand cultivations in lettuce are required when pronamide is used; (3) that pronamide, like propham, must be activated by water; and (4) that the list of alternate pesticides used in clover was incomplete.

The Agency rejects PPG's arguments (1) through (3) above for the following reasons. It is true that very wet fields cannot be worked, regardless of the pesticide used; however, pronamide does offer an advantage in that it can be sprayed onto the wet soil sooner than its alternates. Propham and chloropropham require cultivation into the soil, a practice which cannot be carried out on wet soils.

It was not the intent of the Agency to indicate that mechanical or hand cultivations will be eliminated by the use of pronamide. However, the Agency does believes that fewer mechanical and hand cultivations are required with use of pronamide and that this reduction in mechanical and hand cultivations increases the benefits to the growers.

It is true that water is necessary to activate both pronamide and propham. However, propham is volatile and can lose effectiveness through volatilization unless it is incorporated or watered-in; pronamide can remain in dry soil without loss of effectiveness. This property of pronamide is critically important in alfalfa fields in the Northwest, which are dependent entirely upon rainfall.

The Agency accepts PPG's argument (4) above and grants that the availability of chloropropham for weed control in all clovers was overlooked in PD 2/3. However, this does not alter any of the Agency's conclusions concerning comparative benefits since chloropropham has drawbacks similar to propham.

C. Comments Relating to Regulatory Options

1. Classification for Restricted Use and Requirement for Certified Applicators

Rohm and Haas argued that since the Agency's primary objective was to keep pronamide out of the hands of unskilled homeowners, other measures short of classification for restricted use can be used to achieve that goal. Specifically, Rohm and Haas proposed label directions such as "Not for Home Use" or "For Commercial Crop Production Only" and contended that these directions would successfully keep the product from getting into the hands of the unskilled and untrained. EPA rejects this argument on the grounds that relabeling is insufficient insurance against mishandling of pronamide by lay users.

Rohm and Haas, Secretary of Agriculture Bergland, and Dr. Gordon Harvey commented that overuse of the restricted use classification would reduce its significance.

The Agency rejects this comment and holds that the potential impact of a pesticide, not the number of times any particular regulatory classification has been used, must determine regulatory decisions. The primary reason for assigning a restricted use classification to pronamide is the oncogenic hazard posed to applicators due to the dustiness of the wettable powder formulation.

Dr. Harvey also argued that pronamide did not meet the criteria for restricted use, claiming pronamide presents a low hazard to wildlife and has a low potential for bioaccumulation.

The Agency rejects this argument. Whether or not Dr. Harvey's claim is correct, hazard to wildlife and potential for bioaccumulation are only two criteria for restricting the use of a pesticide. FIFRA, Section 3(d)(1)(c), also lists applicator hazard as a criterion for restricted use, and it is on the basis of applicator hazard that the Agency has proposed to restrict the use of pronamide.

Rohm and Haas has argued that granular formulations should be exempt from restricted use classification because these formulations do not pose the same dermal and inhalation hazard as wettable powders.

After reviewing the available data on particle size in the granular formulation, the Agency agrees that granular products in fact do not represent as great a hazard to the applicator as wettable powders. Accordingly, granular formulations of 1% or less are excluded from a restricted use classification at this time. However, to minimize exposure, the directions for use of granular formulations on turf will be modified to indicate that the pronamide should be watered-in within 24 hours after application.

2. Required Use of Protective Clothing During the Mixing and Application of Pronamide Wettable Powder

Generally, all comments received on the Agency's requirement regarding use of protective clothing were favorable. However, the following comments were made regarding specific aspects of the requirement.

Rohm and Haas argued that only mixers and hand-spray applicators should be required to wear protective clothing since professional applicators routinely wear the protective clothing specified in PD 2/3.

The Agency rejects the argument on the grounds that exposure will not be reduced by limiting the requirement for protective clothing to professional applicators. The Agency agrees that professional applicators are more likely to wear at least some protective clothing than are nonprofessional custom applicators who are involved

in hand spraying; nonetheless, a uniform requirement for protective clothing will insure protection for all applicators, professional and nonprofessional alike.

Secretary of Agriculture Bergland suggested modifying the requirement for fabric gloves to include neoprene gloves. The Agency will accept this modification since neoprene will provide as effective a barrier to dermal exposure as would cloth.

Secretary of Agriculture Bergland and Dr. Gordon Harvey suggested that the requirement for "one-piece protective clothing" be modified to include protective clothing such as coveralls and overalls with long-sleeved shirts because one-piece clothing is not available in all areas of the country.

The Agency has reviewed available information and has concluded that clothing other than one-piece clothing can offer adequate protection to the applicator. The Agency also realizes that, in the absence of one-piece clothing, individuals will wear available work clothes. Consequently, by broadening the definition to include coveralls and overalls with long-sleeved shirts, the Agency is providing additional impetus to the applicator to protect himself.

3. Required Formulation of Pronamide (Wettable Powder) in Water-Soluble Bags

Rohm and Haas, Secretary of Agriculture Bergland, the Scientific Advisory Panel, and Dr. Gordon Harvey objected to the Agency's requirement that wettable powder formulations must be packaged in water-soluble bags, on the basis that (1) the Agency's estimates of applicator exposure are unrealistically high, and (2) exposure data are too incomplete to demonstrate any significant risk.

The first argument has been addressed in Section II above. The Agency has concluded that the new data submitted by Rohm and Haas are fragmentary and inconclusive, and that such data fail to justify any downward adjustment of exposure projections. The second argument, that available exposure data are incomplete, is factually correct. The Agency points out, however, that the affirmative burden of proof lies with the registrant, not with EPA. Because the exact amount of exposure involved is uncertain, the Agency based its regulatory decision concerning water-soluble packaging upon reasonably conservative exposure estimates.

In Position Document 2/3, the Agency's reasons for requiring water-soluble bags for wettable powder formulations are set forth in detail . In summary, this new packaging technology is highly effective in that it virtually eliminates applicator contact with wettable powder formulations during mixing operations, thereby eliminating the

primary source of applicator exposure[2/]. The costs of water-soluble packaging are small, approximately 50 cents per acre and application costs as stated in PD 2/3 are approximately $70 acre, which the Agency estimates will result in less than a 1% increase in application costs. In addition, since the publication of Position Document 2/3, Rohm and Haas has in fact applied for conditional registration of a wettable powder pronamide product which will be packaged in water-soluble packaging.

For these reasons, the Agency has decided to retain the requirement for water-soluble packaging for wettable powder formulations and hereby specifies a two-year implementation period. In the Agency's judgement, two years should be a more than adequate amount of time for an orderly and efficient transition. If however, during the implementation period for water-soluble packaging, Rohm and Haas develops another technology which will essentially eliminate applicator exposure at comparable costs, it should be brought to the Agency's attention. The Agency would then consider modifying or eliminating the requirement for water-soluble packaging[3/].

2/ The projected application exposure without water-soluble packaging would result in an increased lifetime risk of cancer in the range of 10^{-4} for applicators wearing protective clothing.

3/ Rohm and Haas objected to the requirement that it implement an exposure reduction approach selected by the Agency, and argued that the registrant should be permitted to determine the mechanism for exposure reduction. This objection overlooks the fact that the Agency cannot impose exposure reduction requirements in a vacuum. Under the statute, the Agency is required to assess the risk and benefit consequences of specific options, and select an option which achieves a balance between risks and benefits.

4. Cancellation of Hand-Spraying Uses

Secretary of Agriculture Bergland, Rohm and Haas, and the SAP objected to the cancellation of all hand-spray uses as proposed in PD 2/3. The grounds for objection were (1) that hand-spray application is important in the minor uses such as uses on ornamentals and nursery stock and (2) that protective clothing can be employed to reduce exposure to acceptable levels.

The Agency acknowledges that hand-spray uses of pronamide may be crucial for ornamental and nursery stock uses and that protective clothing can provide hand-spray users some protection from exposure to pronamide. However, the remaining hand-spray uses present a different setting of higher risks with no offsetting benefits. The data indicate that for these uses mechanical application methods are predominant. In view of the above, the Agency will rescind its decision to cancel hand-spray uses for ornamentals and nursery stock.

5. Revision of Tolerance on Lettuce to 1 ppm, Extension of the Time-to-Harvest (THI) to 60 Days, and Limitation of Applications to Pre-emergent Use

All commenters agreed with the provision to reduce the tolerance on lettuce to 1 ppm.

However, Rohm and Haas and Secretary of Agriculture Bergland objected to the label restrictions designed to insure that the 1 ppm tolerance would not be exceeded. Rohm

and Haas contends that label restrictions are unnecessary and that their company's evaluation of the data indicates that current label directions are sufficient to insure the proposed tolerance of 1 ppm is not exceeded. The Secretary of Agriculture agreed with Rohm and Haas.

EPA disagrees with the Rohm and Haas' opinion that the current label directions, which require a 35-day time-to-harvest interval, are sufficient to insure that a tolerance of 1 ppm will not be exceeded. Before proposing the label restrictions described in PD 2/3, EPA reviewed Rohm and Haas' data and concluded that the data presently available do not support a 1 ppm tolerance on lettuce without a 60-day time-to-harvest interval and a limitation to pre-emergent use.

The Agency acknowledges there are indications in the original data base that a 1 ppm tolerance might be supported by a label less restrictive than that proposed in PD 2/3. While some of the residues reported exceeded the proposed 1 ppm tolerance, virtually none of these were significantly higher.

The Agency will require the registrant to provide residue data on "head" and "leaf" lettuce, following both pre-emergent and post-emergent applications of pronamide, and residue data on "transplant" lettuce following post-emergent

treatment. All studies must use a minimum THI of 35 days. The studies must be conducted on samples of lettuce grown during the spring/summer in California and New Jersey and during fall/winter in California. The Agency will require these data to be submitted no later than September 1, 1980.

The Agency has decided not to require modification of the THI and not to limit applications to pre-emergent use until these data have been submitted to the Agency. The Agency will use these data to set a 1 ppm tolerance with the least restrictive measures which will still protect the public health . In order to facilitate an expeditious regulatory response once the data are submitted, the Agency will immediately start the tolerance revision process. However, no tolerance revision will be finalized until the residue data have been submitted and evaluated.

6. Required 5-Year Monitoring of Pronamide Residues in Cow's Milk

Rohm and Haas and the SAP note that present data support the 0.02 ppm tolerance for milk. Rohm and Haas has also stated that they would carry out additional studies to broaden the data base, if needed.

In PD 2/3 the Agency reviewed the current potential for residues in milk and the risks posed from those residues. On the basis of the SAP comments that these

studies were unnecessary, the Agency has re-analyzed the data on an absolute worst-case basis. Using a percentage of crop treatment of 10%, the lifetime risk of developing a tumor from pronamide residues in milk is 9.70×10^{-8} (Rossi, 1979). The current lifetime risk at 0.5% of crop treatment is 8.90×10^{-9}. Given this low level of hazard, even if pronamide's use on alfalfa were to increase 20 times, risk would remain negligible. The risk remains negligible even when the remainder of the lifetime dietary risk is factored into the lifetime dietary risk from milk. The Agency therefore rescinds the requirement for monitoring.

III. Conclusions

After reviewing comments from the Secretary of Agriculture, the Scientific Advisory Panel, and others who commented on EPA's findings and recommendations concerning pronamide as set forth in PD 2/3, the Agency has decided to implement Option 4 as put forward in PD 2/3 and restated in Section 1 of this document with the following modifications:

1. Pronamide as a 1% granular formulation with fertilizer will not be classified for restricted use, but labeling for these products must stipulate that watering-in within 24 hours will be required for uses on turf.

2. Protective clothing will still be required during the mixing and application of pronamide as a wettable powder. Use of rubber or fabric gloves will be required. Boots will be required for hand-spray applicators of pronamide.

3. The manufacturer will be allowed two years to implement water-soluble packaging for wettable powder formulations. Specific labeling modifications must be adopted.

4. The cancellation of hand spraying in all uses will be modified to allow hand-spray applications of pronamide only on ornamentals and nursery stock.

5. The Agency will start the tolerance revision process to lower the toelrance from 2 ppm to 1 ppm. Residue studies will be required to provide data to establish the least restrictive labeling modifications to insure that all pronamide residues on lettuce will fall within the 1 ppm tolerance. The tolerance revision will not be finalized until the new residue data is received and evaluated by the Agency.

6. The requirement for monitoring of milk at 5-year intervals will be rescinded.

With the above modifications, Option 4 of PD 2/3 is amended as follows:

1. Cancellation and denial of registrations of hand-spray application of pronamide for all uses except ornamentals and nursery stock.

2. Cancellation and denial of registrations of all pronamide products registered for use on lettuce, alfalfa, and forage legume and other uses unless the registrant or applicant for registration agrees to modify the terms and conditions of registration as follows:

   A. Classification of pronamide wettable powder for Restricted Use Only, for use only by or under the direct supervision of Certified Applicators and only for those uses covered by the Certified Applicators certification.

   B. Modification on the labeling of pronamide wettable power products to include the following:

   (1) Restricted Use Pesticide

   For retail sale to and use only by certified applicators or persons under their direct supervision and only for those uses covered by the Certified Applicators certification.

   (2) General Precautions

   a. Take special care to avoid contact with eyes, skin, or clothing.

b. Wash clothing and gloves after use.

(3) Protective Clothing

The following items of clothing are required when mixing or applying pronamide:

a. Long-sleeved shirts and long pants, preferably one piece (overalls).

b. Hat with brim.

c. Heavy-duty fabric or rubber work gloves.

d. Hand-spray applications of pronamide will require the use of heavy-duty leather or rubber boots.

(4) Water-Soluble Packaging

For all wettable-powder products introduced in commerce after Nov 26 1981, the statement:

"Dilution Instructions"

The enclosed pouches of this product are water soluble. Do not allow pouches to become wet prior to adding to the spray tank. Do not handle the pouches with wet hands or gloves. Always reseal overwrap bag to protect remaining unused pouches. Do not remove water soluble pouches from overwrap except to add directly to the spray tank.

Add the required number of unopened pouches as determined by the dosage recommendations into the spray tank with agitation. Depending on the water temperature and the degree of agitation, the pouches should dissolve completely within approximately five minutes from the time they are added to the water.

C. Modification of the granular formulation pronamide labels to include the following for turf use. "This product should be watered in within 24 hours."

In addition to these provisions, the Agency will start the tolerance revision process to amend the lettuce tolerance from 2 ppm to 1 ppm and will require residue data[4/] to determine if the 1 ppm tolerance can be supported with less restrictive measures than a THI of 60 days and a limitation to pre-emergent use. This data will include residue studies on "head" and "leaf" lettuce after both pre-emergent and post-emergent treatments and on "transplant" lettuce after post-emergent treatment with a time-to-harvest interval of at least 35 days for all the studies. These samples must be from lettuce grown during the spring/summer in California and New Jersey and during the fall/winter in California.

4/ The Agency's requirement for additional studies under Section 3(c)(2)(b) is not challengeable in any Hearing held concerning the cancellation of pronamide registrations or denial of pronamide applications for registration.

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Appendix A

FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT (FIFRA)

SCIENTIFIC ADVISORY PANEL

Review of Notice of Determination Concluding
the Rebuttable Presumption Against Registration (RPAR)
of Pesticide Products Containing Pronamide

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel has completed review of plans by the Environmental Protection Agency (EPA) for initiation of regulatory action on pronamide pesticide products under the provisions of Section 6(b) of FIFRA as amended. The review was completed after open meetings were held in Arlington, Virginia, during the periods January 25-26, 1979, and February 14, 1979.

Maximum public participation was encouraged during formal review of the RPAR on pronamide by the Scientific Advisory Panel. Federal Register notices announcing Panel meetings for review of pronamide were published on October 30, 1978; January 5, 1979; January 18, 1979; and February 7, 1979.

The meeting announced in the Federal Register notice dated October 30, 1978, for November 15 and 16, 1978, was cancelled and rescheduled for January. The Panel was unable to complete review of the regulatory package on pronamide during the meeting held on January 25-26, 1979. Consequently, final action on pronamide was deferred until February 14, 1979. In addition, telephone calls and special mailings were sent to the general public who had previously expressed an interest in activities of the Panel. Written statements relative to regulatory action on pronamide were received over a period of several weeks from the Rohm and Haas Company; the Carcinogen Assessment Group of EPA; and EPA technical staff. In addition, oral comments were received from Rohm and Haas technical staff; EPA technical staff; representatives of the University of California Extension Service; and USDA staff.

In consideration of all matters brought out during Panel meetings, matters detailed in written and oral statements, and careful study of all documents submitted by the Agency, the Panel submits the following report on pronamide:

The fact that pronamide is oncogenic only in the liver of male mice suggests pronamide is at best a weak carcinogen in man.

1. However, because of the potential oncogenicity of pronamide in man, the Panel concurs with the EPA position that pronamide should be classified as a restricted use pesticide.
2. The Panel believes that the hand spray use of pronamide for nursery and ornamental purposes is an important "minor use" and should be allowed to continue with the specification that protective clothing be used by hand spray operators.

3. The Scientific Advisory Panel endorses the statement proposed by EPA to be placed on the labels of pronamide wettable powders, with special emphasis on the use of protective clothing as outlined in the regulatory decision:

a. Take special care to avoid getting pronamide in eyes, on skin, or on clothing.

b. The following items of clothing to be required when applying pronamide.

(1) Long-sleeved, one-piece protective outergarment.

(2) Hat with brim.

(3) Heavy-duty fabric workgloves.

(4) Replace any contaminated clothing.

c. This product is in a water-soluble bag.

Do not break open bag prior to use.

Do not use in quantities smaller than one full bag.

If bag is leaking, use extreme care in handling.

Do not get in eyes, on skin, or on clothing.

However, the Scientific Advisory Panel believes that the requirement for formulation of pronamide in water-soluble bags is unnecessarily restrictive. In our opinion, water-soluble bags or other changes in formulation should be required only if, as determined in field trials, the exposure of applicators to pronamide when wearing proposed protective clothing exceeds that considered by EPA to be acceptable.

4. The Scientific Advisory Panel agrees that the pronamide tolerance on lettuce should be reduced to 1 ppm.

5. Concerning the time-to-harvest interval (THI), the Panel is of the opinion that the subject of the THI should be reexamined by EPA in consultation with the manufacturer. As a result of these consultations, the requirement for the 60-day THI should be reassessed. If the data ensures that pronamide levels will not exceed the tolerance, a shorter THI is encouraged. This will allow more flexibility to growers in the use of this product.

6. The Panel advises that EPA, in consultation with the manufacturer, reexamine the proposed requirement for market basket surveys of pronamide levels in milk at five-year intervals. Experiments performed in cattle by the manufacturer in using alfalfa contaminated with pronamide at the current tolerance level suggests the proposed monitoring need not be done.

7. The Panel believes that postemergence use of pronamide on transplant lettuce should be allowed if the residues at harvest do not exceed the 1 ppm tolerance.

FOR THE CHAIRMAN:

Certified as an accurate report of findings:

H. Wade Fowler, Jr., Ph.D.

Executive Secretary

FIFRA Scientific Advisory Panel

Date: February 14, 1979

Appendix B

Honorable Douglas M. Costle
Administrator, U.S. Environmental
Protection Agency
Washington, D.C. 20460

Dear Mr. Costle:

This is the United States Department of Agriculture's response to the U.S. Environmental Protection Agency's (EPA) Notice of Determination pursuant to 40 CFR 162.11(a)(5), concluding the Rebuttable Presumption Against Registration (RPAR) of Pesticide Products Containing Pronamide, and EPA's proposed intent to cancel and/or modify the terms and conditions of registration, pursuant to Section 6(b)(1) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

The Department of Agriculture and State Cooperators, under the National Agricultural Pesticide Impact Assessment Program (NAPIAP), recognize the need to interact with EPA in developing biological, economic, and exposure information according to the current Memorandum of Understanding between the Department and the Agency. We are also pleased to have the opportunity to review and comment on the Notice of

Determination and the accompanying position document. We are dedicated to the mutual resolution of issues including health risks to applicators, farm workers, and consumers as well as possible adverse impacts on wildlife, non-target organisms, and/or the environment.

We concur with EPA's selection of regulatory options that are consistent with the biological and economic assessments. We, therefore, commend the decision that the registered uses of pronamide are important and meet the requirements for continued registration. The Department agrees that the reduction in the lettuce tolerance from 2 ppm to 1 ppm will continue to provide effective consumer protection.

The issues of concern to the Department and cooperating States and our recommendations relative to the regulatory actions proposed in the Notice of Determination are as follows:

1. "Restricted Use" Classification: The Department does not concur with the proposal to classify pronamide as a "Restricted Use" pesticide. The information presented to users from the certification program for general and restricted use is that classification for "Restricted Use" implies a definite concern over and above the normal precautions exercised in the handling, mixing, and application of pesticides. These precautions have been emphasized by registrants in labeling and in the educational programs of Cooperative Extension for many years. As far as is known, there is no appreciable hazard from the registered uses of pronamide to wildlife or the environment. It has low acute oral toxicity, is not water soluble, has relatively short soil

residual activity and other hazards are relatively low. "Restricted Use" classification would not reduce the rate of treatment, the amount of residue in the crop or the exposure to workers. The lowest effective rate is already being used and therefore residues in the crop would not be affected.

We support the concept of "Restricted Use" and have devoted considerable time and funding to the development of State programs for certification. However, we believe that this classification should be limited to those pesticides that, when used as directed, pose a substantial risk to the user and/or the environment. We do not believe that pronamide falls into this category and feel strongly that a classification of "Restricted Use" may further dilute the sense of caution that should accompany "Restricted Use" pesticides.

Further the Department disagrees with classifying pronamide as a "Restricted Use" pesticide because it will unnecessarily hamper the development of a herbicide that is still expanding in potential. This classification will discourage many current and potential users, particularly small farmers, from using or adopting a practice that could be of great benefit.

2. Prohibiting Hand Spraying: The Department does not concur with the proposed label statement prohibiting hand spraying. Prohibiting this application method reduces the flexibility of pronamide use and eliminates its potential benefits in "minor use" areas of nursery and ornamental weed control. Hand spraying

involves only a small volume of spray material. It is used infrequently and on limited acreages. In our judgment, the use of normal protective clothing during mixing/loading and application will afford an acceptable level of exposure protection to the applicator. an acceptable level of exposure protection to the applicator.

3. Protective Clothing: We do not concur with some of the "protective clothing" statements under the General Precautions section. For example, fabric work gloves may absorb some pronamide and would require frequent washing or replacement. We believe the following precautional statements would provide more adequate protection.

   A. Take special care to avoid getting Pronamide in eyes, on skin, or on clothing.

   B. In case of contact with skin, wash as soon as possible with soap and plenty of water. If clothing is contaminated, remove clothing and wash affected parts of the body with soap and water.

   C. Wear clean clothes each day and launder separately before reusing. At the end of the day, bathe entire body with soap and water.

   D. Required protective clothing for mixing/loading, or mixing/loading and application with hand sprayers:

      1. Long sleeved shirts and long pants, preferably one piece (coveralls).

      2. Rubber (or neoprene) gloves.

3. Boots - for hand applicators.

4. Closely woven hat with brim.

4. Wettable Powder Formulation in Water Soluble Bags: It would be expected that the use of water soluble bags will reduce exposure of those mixing the chemical. There is some question, however, whether the hazard potential requires this measure and whether the technology is sufficiently advanced and the inherent concerns sufficiently understood to justify this regulatory option. The questions which should be addressed include: (1) what are the added costs; (2) do the water soluble bags dissolve instantly or will there be a problem with sprayer operation; and (3) what losses may be incurred or human/environmental hazards created if the water soluble bags are inadvertently exposed to high humidity, dew, rain or damp storage. These considerations should be fully explored with the registrant or the registrant given the option of solving the concern of exposure by other formulation or packaging methods. Additionally, the one-pound bag size limitation will create disposal problems for small growers, as well as economic loss because more spray will be mixed than is utilized for limited size acreages, which will impact the small growers and the hand spray applications of pronamide.

5. Minimum 60-day preharvest interval for lettuce: In light of data showing residue levels in lettuce below the 1 ppm level when applied at intervals down to 35 days preharvest, the 60-day

preharvest interval is unduly restrictive. Such a regulatory action will deprive many lettuce producers of utilizing an effective management tool in their production programs and will significantly increase costs of production because of increased hand-labor requirements. It will also severely impact the growers of early varieties and those who have switched to transplant programs because of the availability of pronamide for effective weed control. We believe that pre- and post-emergence treatments are necessary for effective utilization of pronamide by lettuce producers and should be continued with the reduced tolerance level applying to all situations.

We are confident EPA will give favorable consideration to these suggestions and recommendations in developing the final pronamide regulatory decisions. The opportunity to have cooperated on this important agricultural matter is very much appreciated by us as well as the whole agricultural community. Please let us know if additional information would be helpful.

Sincerely,

Bob Bergland
Secretary

ENVIRONMENTAL PROTECTION AGENCY

(OPP - 30000/14C)

NOTICE OF INTENT TO CANCEL REGISTRATIONS AND DENY APPLICATIONS FOR REGISTRATION OF PESTICIDE PRODUCTS CONTAINING PRONAMIDE PURSUANT TO THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

AGENCY: Office of Pesticide Programs, Environmental Protection Agency (EPA).

ACTION: Notice of Intent to Cancel Registrations and Deny Applications for Registration of Pesticide Products Containing Pronamide; Analysis of Comments (Position Document 4) Concerning Pronamide.

SUMMARY: On May 20, 1977, the Environmental Protection Agency published in the FEDERAL REGISTER (42 FR 25906) a notice of rebuttable presumption against registration and continued registration (RPAR) of pesticide products containing pronamide. Registrants and other interested persons were provided the opportunity to submit data and information to rebut the presumption. After reviewing all available information, the EPA determined that the cancer risk presumption announced in the pronamide RPAR had not been rebutted, and that the uses of pronamide posed risks of cancer to certain exposed groups. The Agency also reviewed information relating to benefits of these uses and, after considering risks in relation to benefits, determined that these risks

may be reduced by modifying the terms and conditions of registration for some uses. These preliminary decisions were announced in the Notice of Determination and Availability of Position Document on Pronamide published on January 15, 1979 [44 FR 3083](The "Preliminary Notice"). Thereafter, a comment period was provided.

This Notice initiates actions to cancel the pronamide registrations or deny applications unless the terms and conditions of registration are modified as follows: (1) the cancellation and denial of registrations of hand spray application of pronamide for all uses except ornamentals and nursery stock; (2) the classification of pronamide wettable powders for restricted use and the requirement for applicator certification; (3) the amendment of the labeling for pronamide (wettable powder) to require the use of protective clothing during the mixing and application of pronamide; (4) the requirement for the packaging of pronamide wettable powder in water soluble bags; (5) precautionary labeling on pronamide wettable powder formulations; and (6) amendment of the granular formulation labels for turf use.

In addition to these modifications in the terms and conditions of registration, the Agency will start the tolerance revision process to amend the lettuce tolerance

from 2 ppm to 1 ppm and will require the submission of residue data to determine if the 1 ppm tolerance can be supported with less restrictive measures than a THI of 60 days and a limitation to pre-emergent use.

FOR FURTHER INFORMATION CONTACT: Richard Troast, Project Manager, Special Pesticide Review Division, Office of Pesticide Programs (TS-791), Room 711E, Crystal Mall #2, EPA (703-557-7420).

SUPPLEMENTARY INFORMATION: Position Document 4 (PD 4), which accompanies this Notice, discusses in detail the comments which were received concerning Position Document 2/3 (PD2/3) and the Preliminary Notice which accompanied PD 2/3. The comments of the FIFRA Scientific Advisory Panel and the Secretary of Agriculture are included in their entirety as Appendices to PD 4.

I. INTRODUCTION

On Janu ry 6, 1979 (43 FR 3083, January 15, 1979) the Environm l Protection Agency issued a Notice of Determination "Preliminary Notice") pursuant to 40 CFR 162.11(a terminating the pronamide RPAR. The Preliminary N e was accompanied by a Position Document (PD) 2/3 ch set forth in detail the Agency's

from 2 ppm to 1 ppm and will require the submission of residue data to determine if the 1 ppm tolerance can be supported with less restrictive measures than a THI of 60 days and a limitation to pre-emergent use.

FOR FURTHER INFORMATION CONTACT: Richard Troast, Project Manager, Special Pesticide Review Division, Office of Pesticide Programs (TS-791), Room 711E, Crystal Mall #2, EPA (703-557-7420).

SUPPLEMENTARY INFORMATION: Position Document 4 (PD 4), which accompanies this Notice, discusses in detail the comments which were received concerning Position Document 2/3 (PD2/3) and the Preliminary Notice which accompanied PD 2/3. The comments of the FIFRA Scientific Advisory Panel and the Secretary of Agriculture are included in their entirety as Appendices to PD 4.

I. INTRODUCTION

On January 6, 1979 (43 FR 3083, January 15, 1979) the Environmental Protection Agency issued a Notice of Determination (the "Preliminary Notice") pursuant to 40 CFR 162.11(a)(5), terminating the pronamide RPAR. The Preliminary Notice was accompanied by a Position Document (PD) 2/3 which set forth in detail the Agency's

analysis of rebuttal comments to the RPAR. In this PD 2/3 the Agency determined that the risks of using pronamide are greater than the social, economic, and environmental benefits of these uses, unless risk reductions are accomplished by modifications in the terms or conditions of registration. The Agency further determined that these modifications in the terms and conditions of registration accomplish significant risk reductions, and that these can be achieved without significant impacts on the benefits of the uses. The Agency also recommended that certain studies be performed.

This Notice and accompanying PD 4 set forth in detail the Agency's analysis of the comments submitted by the Secretary of Agriculture, the FIFRA Scientific Advisory Panel (SAP), and other interested parties regarding the reasons and factual bases for the regulatory actions announced in the Preliminary Notice of Determination. The regulatory actions announced in this Notice have been modified, as appropriate, in light of the comments and other information received on PD 2/3 and the preliminary Notice from all sources.

This notice is organized into four Sections. This introduction is Section I. Section II, titled "Legal

Background," is a general discussion of the regulatory framework within which these actions are taken. Section III sets forth the regulatory actions the Agency is implementing concerning pronamide; Section III and the Position Document set forth the bases for the actions. Section IV, titled "Procedural Matters," provides a brief discussion of the procedures which will be followed in implementing the regulatory actions which the Agency is announcing in this notice.

II. LEGAL BACKGROUND

In order to obtain a registration for a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA), a manufacturer must demonstrate that the pesticide satisfies the statutory standard for registration. That standard requires (among other things) that the pesticide perform its intended function without causing "unreasonable adverse effects" on the environment [Section 3(c)(5)]. "Unreasonable adverse effects on the environment" is defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide" [Section 2(bb)]. In effect, the registration standard requires a finding that the benefits from each use of the pesticide exceed the risks from that use, when the pesticide is used in accordance

with commonly recognized practice. The burden of proving that a pesticide satisfies the registration standard is on the proponents of registration (e.g., registrants or users) and continues as long as the registration remains in effect. Under Section 6 of FIFRA, the Administrator is required to cancel the registration of a pesticide or modify the terms and conditions of registration whenever he determines that the pesticide no longer satisfies the statutory standard for registration.[1/]

The Agency created the RPAR process to facilitate the identification of pesticide uses which may not satisfy the statutory standard for registration and to provide a public, informal procedure for the gathering and evaluation of information about the risks and benefits of these uses.

1/ The statutory standard for registration also requires that the pesticide satisfy the labeling requirements of FIFRA. These requirements are set out in the statutory definition of "misbranded" [FIFRA Secton 2(q)]. Among other things, this section provides that a pesticide is misbranded if the "labeling ... does not contain directions for use which are necessary for effecting the purpose for which the product is intended and if complied with, together with any ... [restrictions] imposed under Section 3(d) ... are adequate to protect health and the environment."

The Agency can require changes in the directions for use of a pesticide in most circumstances either by finding that the pesticide is misbranded if the labeling is not changed, or by finding that the pesticide would cause unreasonable adverse effects on the environment unless labeling changes are made which accomplish risk reductions.

The RPAR process is set forth at 40 CFR 162.11. This section provides that a rebuttable presumption shall arise if a pesticide meets or exceeds any of the risk criteria set out in the regulations. After an RPAR is issued, registrants and other interested persons are invited to review the data upon which the presumption is based and to submit data and information to rebut the presumption. Respondents may rebut the presumption of risk by showing that the Agency's initial determination of risk was in error, or by showing that use of the pesticide is not likely to result in any significant exposure to man or the animal or plant of concern with regard to the adverse effect in question.[2/] Further, in addition to submitting evidence to rebut the risk presumption, the respondents may submit evidence as to

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2/ 40 CFR 162.11(a)(4) provides that registrants and applicants may rebut a presumption against registration by sustaining the burden of proving: "(i) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraphs (a)(3)(i) or (iii) that when considered with the formulation, packaging, method of use, and proposed restrictions and directions for use and widespread and commonly recognized practices of use, the anticipated exposure to an applicator or user and to local, regional or national populations of nontarget organisms is not likely to result in any significant acute adverse effects; or (ii) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraph (a)(3)(ii) that when considered with proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist, or accrue to levels in man or the environment likely to result in any significant chronic adverse effects ...; or (iii) that the determination by the Agency that the pesticide meets or exceeds any of the criteria for risk was in error."

whether the economic, social and environmental benefits of the use of the pesticide subject to the presumption outweigh the risk of use.

The regulations require the Agency to conclude an RPAR by issuing a notice of determination. In that notice, the Agency states and explains its position on the question of whether the risk presumption has been rebutted. If the Agency determines that the presumption is not rebutted, it then considers information relating to the social, economic, and environmental costs and benefits which registrants and other interested persons submitted to the Agency, and any other benefits information known to the Agency. If the Agency determines that the risks of a pesticide use appear to outweigh its benefits, the RPAR process finally concludes with a Notice of Intent to Cancel or Deny Registration, pursuant to FIFRA Section 6(b)(1) or Section 3(c)(6).

When the uses of a pesticide appear to pose risks which are greater than benefits, the Agency considers modifications to the terms and conditions of registration which can reduce risks, and the impacts of such modifications on the benefits of the use. The risk reduction measures, short of cancellation, which are available to the Agency, include requiring changes in the directions for use on the pesticide's labeling, and classifying the pesticide for "restricted use," pursuant to FIFRA, Section 3(d).

The statute requires the Agency to submit notices issued pursuant to Section 6 to the Secretary of Agriculture for comment and to provide the Secretary of Agriculture with an analysis of the impact of the proposed action on the agricultural economy [Section 6(b)]. The Agency is required to submit these documents to the Secretary at least 60 days before making the notice effective by sending it to registrants or making it public. If the Secretary of Agriculture comments in writing within 30 days of receiving the notice, the Agency is required to publish the Secretary's comments and the Administrator's response together with the Notice. The statute also requires the Administrator to submit Section 6 notices to a Scientific Advisory Panel (SAP) for comment on the impact of the proposed action on health and the environment, at the same time and under the same procedures as those described for review by the Secretary of Agriculture [FIFRA Section 25(d)].

Although not required to do so under the statute, the Agency decided that it is consistent with the general theme of the RPAR process and the Agency's overall policy of open decisionmaking to afford an opportunity to registrants and other interested persons to comment on the bases for the proposed action during the time that

the proposed action is under review by the Secretary of Agriculture and the Scientific Advisory Panel (SAP). Accordingly, the Preliminary Notice and PD 2/3 were published in the Federal Register and made available to registrants and other interested persons at the time the decision documents were transmitted for formal external review. Registrants and other interested persons were allowed the same period of time to comment, 30 days, that the statute provides for receipt of comments from the Secretary of Agriculture and the SAP.

III. DETERMINATIONS AND ANNOUNCEMENT OF REGULATORY ACTIONS

As detailed in the Preliminary Notice and PD 2/3, the Agency considered information on the risks associated with the use of pronamide, including information submitted by registrants and other interested persons in rebuttal to the pronamide RPAR. The Agency also considered information on social, economic and environmental benefits of the uses of pronamide subject to the RPAR, including benefits information submitted by registrants and other interested persons in conjunction with their rebuttal submissions and information submitted by the United States Department of Agriculture. The Agency's assessment of the risks and benefits of the uses of pronamide subject to this RPAR, its conclusions and determinations on

whether any uses of pronamide pose unreasonable adverse effects on the environment, and its determinations on whether modifications in terms or conditions of registration reduce risks sufficiently to eliminate any unreasonable adverse effects, were set forth in detail in PD 2/3. The PD 2/3 was adopted by the Agency as its statement of reasons for the determinations and actions previously announced in the Notice of Determination and as its analysis of the impacts of the proposed regulatory actions on the agricultural economy.

This Notice constitutes the Agency's Final Notice of Determination Concluding the Pronamide RPAR. It reflects any modifications in the Agency's initial determinations on the risks and benefits of pronamide pesticide uses which the Agency has concluded are appropriate, after review of the comments and information received concerning PD 3 and the Preliminary Notice from the Secretary of Agriculture, the SAP, and other sources. This Notice also reflects the modifications in the regulatory actions announced in the Preliminary Notice which the Agency has concluded are appropriate, in light of the comments and other information received on PD 3 and the Preliminary Notice from all sources. PD 4, which accompanies this Notice, discusses in detail the information that was

received,[3/] and the Agency's reasons for changing or not changing its initial determinations and the regulatory actions announced in the Preliminary Notice. Finally, this Notice announces the regulatory actions which the Agency is implementing concerning pronamide. The Agency hereby incorporates PD 3 and PD 4 as its statement of reasons for these actions.

A. Determinations on Risks

The pronamide RPAR was based on laboratory studies showing that pronamide induced oncogenic effects in experimental mammalian species. The Agency has determined that the presumption that pronamide poses an oncogenic risk was not rebutted. The Agency has further determined that human exposure may result from the uses of pronamide, and that pronamide use therefore poses a cancer risk to man of sufficient magnitude to require the Agency to determine whether the uses of pronamide offer offsetting social, economic, or environmental benefits. The Agency identified the key populations at risk with respect to pronamide use: the U.S. population at large, and pesticide applicators.

3/ The comments from the SAP and the Secretary of Agriculture are attached as appendices to PD 4. All other comments are available in the pronamide public file for inspection and review.

B. Determinations on Benefits

The uses of pronamide which are subject to this notice are grouped into three categories: lettuce use, alfalfa use, and other uses.[4/]

1. Lettuce Use

Pronamide is used on lettuce to control a variety of weeds and grasses. Most of the pronamide used for lettuce (70%) is used in Arizona and California. Significant adverse economic impacts would result if pronamide were unavailable for this use and alternate methods of weed control were employed. Pronamide offers a wider spectrum of activity than its alternates; thus, if pronamide were unavailable, more pesticides would be applied to control weeds. Pronamide also offers a wider versatility of application methodology than the alternatives, and timing is not as critical to assure maximum effectiveness. Finally, pronamide is more biologically active than the alternatives and thus the use of this pesticide reduces the frequency of field reentry to mechanically control weeds which develop after herbicide application.

4/ The category of "other uses" consists of these agricultural crops: blueberries, boysenberries, raspberries and other cane fruit, sugar beet grown for seed, ornamental nursery stock, christmas tree plantings and ornamental turf.

2. Alfalfa and Other Forage Legumes

In alfalfa, pronamide offers growers control of one noxious weed, quackgrass, for which there are no alternatives presently registered. Non-chemical control methods are also generally ineffective, as well as costly to the grower.

Pronamide also offers some increase in utility over alternatives to alfalfa growers similar to that achieved in lettuce use, since its use does not require critical timing to insure maximum effectiveness for control of weeds.

3. Other Uses

The ability and utility of pronamide to control weeds (berries, ornamental turf, and nursery stock) for these "other uses" is similar to that of lettuce and alfalfa. There are few, if any, alternatives which can be used to adequately control weeds more efficiently and economically than pronamide.

C. Determinations on Unreasonable Adverse Effects

For the reasons set forth in detail in the PD 2/3, as discussed and modified in PD 4, the Agency has made the following unreasonable adverse effect determinations with respect to the uses of pronamide subject to this RPAR:

1. Determinations on All Wettable Power Formulations

The Agency has determined that the risks resulting from the use of the wettable powder formulations are greater than the social, economic, and environmental benefits of these uses, unless risk reductions are accomplished by modifications in the terms or conditions of registration, as described below. The Agency has further determined that these modifications in the terms and conditions of registration accomplish significant risk reductions, and that these risk reductions can be achieved without significant impact on the benefits of the uses. Accordingly, the Agency has determined that unless changes are made in terms and conditions of registration, the uses of pronamide as a wettable powder will generally cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice, and that the labeling of pronamide pesticide products will not comply with the provisions of FIFRA.

2. Determinations on Granular Formulations for Turf Weed Control

The Agency has determined that the use of pronamide as a granular product poses risks which are greater than the social, economic and environmental benefits of these

uses unless risk reductions are accomplished by modifications in the terms and conditions of registration, as described below. The Agency has further determined that these modifications in the terms and conditions of registration accomplish significant risk reductions, and that these risk reductions can be achieved without significant impact on the benefits of these uses.

Accordingly, the Agency has determined that unless these changes in the terms and conditions of registration are accomplished, the uses of pronamide as a granular formulation will generally cause unreasonable adverse effects on the environment when used in accordance with widespread and commonly recognized practice, and that the labeling of pronamide pesticide products will not comply with the provisions of FIFRA.

D. Other Determinations

Under Section 3(c)(2)(B) of FIFRA the Agency has authority to determine that registrants must conduct certain additional studies as a condition of continued registrations. In the event a registrant fails to take appropriate steps to secure the data required by the Agency, the Administrator may take appropriate action to suspend the registrant's registrations for

which additional data is required. Since requirements that registrants conduct certain studies are imposed pursuant to Section 3(c)(2)(B) and not as terms or conditions of registration pursuant to Section 6(b), the Agency's requirement of certain tests is not challengeable in a Section 6(b) hearing. The Agency has determined that pronamide registrants holding lettuce use registrations must submit the results of the lettuce residue studies detailed in Section III, E. of this Notice to the Agency by September 1, 1980.

E. Announcement of Regulatory Actions

Based upon the determinations summarized above and developed in detail in the PD 2/3 as modified by PD 4, the Agency is initiating the following regulatory actions, and this document shall constitute its notice of intent regarding these actions.

1. Cancellation and denial of registrations of hand spray application of pronamide for all uses except ornamentals and nursery stock.
2. Cancellation and denial of registrations of all pronamide products registered for

use on lettuce, alfalfa and forage legumes and other uses unless the registrants or applicants for registration modify the terms and conditions of registration as follows:[6/]

A. Classification of pronamide wettable powder products for Restricted Use Only, For use only by or under the direct supervision of Certified Applicators and only for those uses covered by the Certified Applicators certification.

B. Modification of the labeling of pronamide wettable power products to include the following:

(1) RESTRICTED-USE PESTICIDE

For retail sale to and use only by

6/ FIFRA Section 6(b)(1) provides that the Administrator may initiate proceedings to cancel a registration or change its use classification, where the Administrator finds that the pesticide does not satisfy the statutory standard for registration. However, the registered pronamide products subject to this action have not yet been initially classified. Accordingly, any classification action with respect to these products is an initial classification and not a change in classification. Initial classification generally does not give rise to a right to review the classification decision in an adjudicatory hearing. [See Preamble to Optional Procedures for Classification of Pesticide Uses by Regulation, 43 FR 5782, 5734 (Feb. 9, 1978)]. However, in view of the fact that the Agency is proposing other changes to the terms or conditions of the registration

certified applicators or persons under their direct supervision and only for those uses covered by the certified applicator's certification.

(2) General Precautions

(a) Take special care to avoid contact with eyes, skin or clothing.

(b) Wash clothing and gloves after use.

(3) Protective Clothing

The following items of clothing are required when mixing or applying pronamide:

(a) Long-sleeved shirts and long pants, preferably one piece (overalls).

(b) Hat with brim.

(c) Heavy-duty fabric or rubber work gloves.

6/ (Footnote continued from previous page)

(e.g. labeling changes) for registered pronamide products, which are reviewable in adjudicatory hearings, the Agency has determined that it is appropriate to exercise its discretion to fashion procedures in excess of minimum statutory requirements, and to permit the question of whether pronamide uses should be initially classified for restricted use and its use limited to certified applicators to be reviewed in any such adjudicatory hearing as well.

(d) Hand-spray applications of pronamide will require the use of heavy-duty leather or rubber boots.

(4) Water-Soluble Packaging

For all wettable-powder products introduced in commerce after _____ _____, the statement:

"Dilution Instructions"

The enclosed pouches of this product are water soluble. Do not allow pouches to become wet prior to adding to the spray tank. Do not handle the pouches with wet hands or gloves. Always reseal overwrap bag to protect remaining unused pouches. Do not remove water soluble pouches from overwrap except to add directly to the spray tank.

Add the required number of unopened pouches as determined by the dosage recommendations into the spray tank with agitation. Depending on the water temperature and the degree of agitation, the pouches should dissolve completely within approximately five minutes from the time they are added to the water.

C. Modification of the granular formulation pronamide labels to include the following for turf use. "This product should be watered in within 24 hours."

In addition to these actions, the Agency will start the tolerance revision process to amend the lettuce tolerance from 2 ppm to 1 ppm and pursuant to Section 3(c)(2)(B) will require residue data to determine if the 1 ppm tolerance can be supported with less restrictive measures than a THI of 60 days and a limitation to pre-emergent use. This data will include residue studies on "head" and "leaf" lettuce after both pre-emergent and post-emergent treatments and on "transplant" lettuce after post-emergent treatment with a time-to-harvest interval of at least 35 days for all the studies. These samples must be from lettuce grown during the spring/summer in California and New Jersey and during the fall/winter in California. The Agency is requiring the submission of the studies by September 1, 1980.

IV. PROCEDURAL MATTERS

This notice initiates actions to cancel the registration of pronamide unless registrants modify the terms and conditions of registration as required by this notice. This notice also notifies applicants for new

registrations that unless the applicant complies with the conditions required by this notice and notifies the Agency of such action within 30 days from receipt by the registrant or publication, the Agency will refuse to approve the application.

Under Sections 6(b) and 3(d) of FIFRA, applicants, registrants, and other interested or affected persons may request a hearing on the cancellation and denial actions that this notice initiates. This section of the Notice explains how affected persons may request a hearing, and the consequences of requesting or failing to request a hearing in accordance with the procedures specified in this notice.

A. Procedure for Requesting a Hearing

1. When a Hearing Must Be Requested for Cancellation Actions

Registrants affected by the actions initiating conditional cancellation of the registered uses of pronamide may request a hearing on specific registered uses within 30 days of receipt of this notice, or on or before _____, whichever occurs later. Any person adversely affected by the cancellation actions initiated by this notice may request a hearing on specific registered uses affected by this notice on or before _____.

2. When a Hearing Must Be Requested for Actions to Deny Applications

Applicants for new registration of the uses affected by this notice may request a hearing on specific uses within 30 days of receipt of this notice, or on or before _____, whichever occurs later. Other interested persons may request a hearing with the concurrence of the applicant during the time period available to the applicant.

3. How to Request a Hearing

All hearing requests must be filed in accordance with the Agency's Rules of Practice Governing Hearings (40 CFR Part 164). Among other things, these procedures require all hearing requests to be accompanied by objections that are specific for each use for which a hearing is requested and to describe the specific product(s) to which the hearing request refers. All requests must be received by the Hearing Clerk within the applicable 30 day time period [40 CFR 164.5(a)]. Failure to comply with these procedures will automatically result in denial of the request for a hearing.

Request for hearings must be submitted to:

Hearing Clerk (A-110)
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

B. Consequences of Filing or Failing to File a Hearing Request

1. Consequences of Filing a Timely and Effective Hearing Request

If a hearing is requested in a timely and effective manner before the end of the 30-day notice periods, the hearing will be governed by the Agency's Rules of Practice for hearings under FIFRA section 6 (40 CFR Part 164). In the event of a hearing, the conditional cancellation and denial actions will not become effective with respect to pesticide products and uses subject to the hearing, except pursuant to orders of the Administrator at the conclusion of the hearing.

2. Consequences of Failure to File in a Timely and Effective Manner

A registrant or applicant for registration who does not file a timely and effective hearing request shall be deemed to have acquiesced in the changes to the terms or conditions of registration required by this Notice. Such registrants

and applicants for registration will receive detailed instructions from the Agency at a later date about how to bring their registrations into compliance with this Notice.

Date: 10/9/85

Steven D. Jellinek
Assistant Administrator
for Toxic Substances